UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

CLARENCE DAVID WRIGHT	)	**Civil Action No.:** 1:18-cv-201
	)	
And	)	
	)	
SHARON K. WRIGHT,	)	**JURY TRIAL DEMANDED**
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
	)	
DAVOL INC., and C.R. BARD,	)	
	)	
	)	
Defendants.		

ORIGINAL COMPLAINT

Plaintiffs CLARENCE DAVID WRIGHT and SHARON K. WRIGHT, by and through their undersigned counsel, bring this Complaint for damages against Defendants Davol Inc., and C.R. Bard, and in support thereof state the following:

1. This is an action brought on behalf of Plaintiffs **CLARENCE DAVID WRIGHT and SHARON K. WRIGHT**, arising out of the failure of Defendants' hernia mesh product. As a result, Plaintiff CLARENCE DAVID WRIGHT has suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

STATEMENT OF PARTIES

2. At all material times Plaintiffs have been citizens and residents of Missouri and the United States.

3. Davol, Inc. ("Davol") is incorporated in Delaware, with its principal place of business in Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including a hernia mesh composed of polypropylene, and an expanded polytetrafluoroethylene (ePTFE) sheet, which is attached to one side the polypropylene mesh (hereinafter "ePTFE Bard Mesh" or "product").

4. C.R. Bard, Inc. ("Bard") is Davol's corporate parent/stockholder. Bard is incorporated and based in New Jersey. It is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices, and controls the largest share of the hernia mesh market. Bard participates in the manufacture and distribution of ePTFE Bard Mesh. It also manufactures and supplies Davol with material that forms part of the ePTFE Bard Mesh.

5. At all material times, Bard was responsible for Davol's actions, and exercised control over its functions, specific to the oversight and compliance with applicable safety standards relating to and including EPTFE Bard Mesh sold in the United States. In such capacity, Bard committed, or allowed to be committed, tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Bard's misfeasance and malfeasance caused Plaintiff CLARENCE DAVID WRIGHT to suffer injury and damages.

6. Defendants are individually, jointly and severally liable to Plaintiff CLARENCE DAVID WRIGHT for damages he suffered, arising from their design, manufacture, marketing, labeling, distribution, sale and placement of the defective ePTFE Bard Mesh at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or

owners, all acting within the course and scope of their agencies, services, employments and/or ownership.

7. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all material times acting on behalf of Defendants and within the scope of their employment or agency.

VENUE AND JURISDICTION

8. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiffs CLARENCE DAVID WRIGHT and SHARON K. WRIGHT and all Defendants. The amount in controversy exceeds $75,000.

9. This Court has personal jurisdiction over each Defendant pursuant to the Missouri Long-Arm Statute, RSMO § 506.500.1(1)-(3). Specifically, Defendants transact business within the State of Missouri, and contracted to sell and supply their ePTFE Bard Mesh products in the State of Missouri, and committed tortious acts and omissions in the State of Missouri. Defendants employ sales representatives in the State of Missouri to sell their products throughout the State, including the ePTFE Bard Mesh implanted in Plaintiff CLARENCE DAVID WRIGHT in Missouri. Defendants' tortious acts and omissions in the State of Missouri caused injury to Plaintiff. Defendants have substantial, systematic and continuous contact with this State such that exercise of personal jurisdiction over these Defendants is appropriate.

10. Defendants have purposefully engaged in Missouri in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or other related entities, medical devices including the ePTFE Bard Mesh, for which they derived significant and regular income. Defendants intended

and reasonably expected that that their defective mesh products, including the ePTFE Bard Mesh, would be sold and implanted in Missouri and could cause injury in Missouri.

11. Further, Davol and Bard are registered to do business in the State of Missouri.

12. Defendants have and continue to conduct substantial business in the State of Missouri and in this District, distribute ePTFE Bard Mesh in this District, receive substantial compensation and profits from sales of ePTFE Bard Mesh in this District, and make material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to in personam jurisdiction in this District.

13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because the events or omissions giving rise to Plaintiff's claims occurred in this District.

FACTS COMMON TO ALL COUNTS

14. On or about September 9, 2011, Plaintiff CLARENCE DAVID WRIGHT underwent repair of a ventral incisional hernia by Dr. Franklin McGinty, M.D., at Southeast Missouri Hospital in Cape Girardeau, Missouri. A 3x3" Composix Mesh, Cat No. 0010203, Lot No. HUVD1398 was implanted in Plaintiff during this repair.

15. Defendants manufactured, sold, and/or distributed the ePTFE Bard Mesh to Plaintiff, through his physician, to be used for treatment of hernia repair.

16. On or about August 8, 2014, Plaintiff CLARENCE DAVID WRIGHT underwent surgery by Dr. Franklin McGinty, M.D., to explant an infected ventral hernia mesh. During the surgery, Dr. Franklin McGinty, M.D., noted that the "previous hernia repair mesh was encountered and was floating in liquified granulation tissue … the mesh was gently teased out of this deep space [as] it was nonadherent." Dr. Franklin McGinty, M.D., stated that the previously placed mesh "was basically rolled up and basically floating free beneath the fascia … [the mesh] was

gently peeled away from the peritoneum and fascia circumferentially and then very carefully peeled away from the small bowel, which it was adherent to … this was done with some difficulty[;]" "further dissection of the mesh using cautery allowed complete excision and removal of the mesh with the abdominal wall wound."

17. Plaintiff continues to experience complications related to the ePTFE Bard Mesh. [He] has already and will likely require additional surgeries to repair the damage from Defendants' product.

18. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of the ePTFE Bard Mesh, including providing the warnings and instructions concerning their product.

19. Among the intended purposes for which Defendants designed, manufactured and sold the product was its use by surgeons for hernia repair surgeries. That was the purpose for which the ePTFE Bard Mesh was implanted in Plaintiff CLARENCE DAVID WRIGHT.

20. The Composix is composed of the following layers:

i) ePTFE sheet

ii) Polypropylene mesh

21. The polypropylene side of the ePTFE Bard mesh was intended to promote incorporation (scarring into the abdominal wall), while the ePTFE side was intended to prevent adhesion formation from the polypropylene being exposed to underlying organs. However, the utilization of ePTFE results in the product being highly prone to infection, while the utilization of polypropylene results in the product being extremely difficult to remove once the ePTFE Bard Mesh becomes infected.

22. For decades, there were concerns in the medical community about severe complications if a foreign object, such as a mesh, was placed too close to the bowel or other underlying organs, due to inflammation in the presence of sensitive organs and the formation of dense adhesions to the device.

23. Defendants represented to Plaintiff and his physician that the ePTFE Bard Mesh was a safe and effective product for hernia repair.

FDA 510(k) CLEARANCE PROCESS

24. The "510(k) clearance process" of the U.S. Food & Drug Administration (FDA) refers to Section 510(k) of the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (MDA). Under this process, medical device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA had approved for sale before 1976 (when the MDA was enacted).

25. No clinical testing or clinical study is required to gain FDA approval under this process. Instead, a given device was supposed to demonstrate substantial equivalence to a predicate medical device.

26. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices.

27. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices the FDA had approved for sale pre-1976 could be sold to patients in a matter of 90 days—without any clinical testing.

28. Therefore, clearance for sale under the 510(k) process does not equate to FDA approval of the cleared medical device.

29. At the request of the FDA in 2012, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, reaching the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

30. The NIH explained: "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to 1976 "did not include any evaluation of the safety and effectiveness of individual medical devices . . .Thus it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

31. Defendants cleared their ePTFE Bard Mesh, and its related components, under the 510(k) Premarket Notification.

32. Defendants failed to comply with the FDA application and reporting requirements.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

33. Due to Defendants' acts of fraudulent concealment, they are estopped from relying on any statutes of limitations or repose. Such acts include Defendants' intentional concealment from Plaintiff CLARENCE DAVID WRIGHT and the general public that the ePTFE Bard Mesh is defective, while continuing to market the product with the adverse effects described in this Complaint.

34. Given Defendants' affirmative actions of concealment by failing to disclose information about the defects known to them but not the public—information over which

Defendants had exclusive control—and because Plaintiff could not reasonably have known the ePTFE Bard Mesh was defective, Defendants are estopped from relying on any statutes of limitations that might overwise be applicable to the claims asserted in this Complaint.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

35. Plaintiff incorporates by reference the allegations in all prior paragraphs as if fully set forth herein.

36. Defendants expected and intended their ePTFE Bard Mesh to reach users such as Plaintiff in the condition in which the product was sold.

37. The implantation of ePTFE Bard Mesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

38. When the ePTFE Bard Mesh was implanted in Plaintiff's body, the product was defectively manufactured.

39. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the ePTFE Bard Mesh implanted in Plaintiff. The implanted product did not conform to Defendants' intended manufacturing and design specifications.

40. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the ePTFE Bard Meshes, which deviated from their material and supply specifications.

41. As a direct and proximate result of Defendants' defective manufacture of the ePTFE Bard Mesh, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

42. Plaintiff incorporates by reference the allegations in all prior paragraphs as if fully set forth herein.

43. Defendants' ePTFE Bard Mesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the product, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components, including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

44. When affixed to the body's tissue, the impermeable ePTFE layer prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

45. The smooth surface of the ePTFE Bard Mesh provides an ideal bacteria breeding ground in which bacteria cannot be eliminated by the body's immune response, thus allowing infection to proliferate.

46. The ePTFE Bard Mesh is defective in its design in part because of a material mismatch. The ePTFE shrinks at a significantly faster rate than polypropylene. This material mismatch results in the ePTFE Bard Mesh curling after implantation.

47. The ePTFE contracts due to the body's inflammatory and foreign body response. Polypropylene incites a greater inflammatory and foreign body response than ePTFE alone.

Defendants' ePTFE and polypropylene combination design results in the ePTFE layer shrinking faster than ePTFE not in the presence of polypropylene would.

48. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the ePTFE Bard Mesh. Although ETO is an effective disinfectant, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores if ETO is used. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores.

49. The ePTFE Bard Mesh, containing spores, will eventually cause an infection after implantation. The spores can remain dormant for extended periods of time, resulting in infections months or years after the ePTFE Bard Mesh was implanted. The following non-exhaustive literature discusses the necessity of moisture during ETO sterilization:

A. In January of 1989, a review on sterilization methods of medical devices was published in the Journal of Biomaterials Applications. ETO was among the sterilization methods reviewed. **ETO was noted to be highly resistant to dry spores, moisture must be present; presoaking most desirable. Experiments demonstrated the importance of the state of humidification of organisms at the time of their exposure to ETO. Desiccation of the spores prior to ETO exposure produces a small but significant percentage of organisms which are highly resistant to the sterilization process. Similar resistance to destruction by ETO occurs in desiccated staphylococcus aureus. Rehumidification of such organisms can require prolonged exposure to an atmosphere having a 50 to 90 percent relative humidity. Moisture has been found to be a critical factor in achieving sterility with gaseous ETO. No gas sterilizer can effectively kill desiccated spores.**

Dempsey, D.J. and Thirucote, R.R., *Sterilization of medical devices: A Review*. Journal of Biomaterials Applications, 3(3), pp. 454-523 (1988). DOI: 10.1177/088532828800300303

50. The multi-layer design of the ePTFE Bard Mesh results in ineffective sterilization more often than with a single layer mesh.

51. The Defendants' ePTFE Bard Mesh product is cytotoxic, immunogenic, and non-biocompatible, causing or contributing to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

52. The solid, flat, relatively smooth and continuous surface of Defendants' ePTFE Bard Mesh inhibits the body's ability to clear toxins.

53. These manufacturing and design defects associated with the ePTFE Bard Mesh were directly and proximately related to the injuries Plaintiff CLARENCE DAVID WRIGHT suffered.

54. Neither Plaintiff nor his implanting physician was adequately warned or informed by Defendants of the defective and dangerous nature of ePTFE Bard Mesh. Moreover, neither Plaintiff nor his implanting physician was adequately warned or informed by Defendants of the risks associated with the ePTFE Bard Mesh product.

55. The ePTFE Bard Mesh implanted in Plaintiff failed to reasonably perform as intended. The product caused serious injury and had to be surgically removed via invasive surgery, necessitating additional invasive surgery to repair the hernia that the product had initially been implanted to treat.

56. When the ePTFE Bard Mesh was implanted in Plaintiff's body, it was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

57. Defendants expected and intended the ePTFE Bard Mesh to reach users such as Plaintiff in the condition in which the product was sold.

58. The implantation of the product in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

59. The risks of Defendants' ePTFE Bard Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The ePTFE Bard Mesh incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable ePTFE layer leads to seroma formation, and provides a breeding ground for infection by protecting bacteria from being eliminated through the body's natural immune response.

60. The polypropylene mesh was in itself dangerous and defective, particularly when used in the product in the manner intended by Defendants in the ePTFE Bard Mesh. The particular polypropylene material used in their product was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions caused by the product. As the ePTFE layer quickly contracts, the ePTFE Bard Mesh curls, exposing the underlying polypropylene. When implanted adjacent to the bowel and other internal organs, as Defendants intended for ePTFE Bard Mesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

61. Bacterial adherence is increased due to the interstitial porosity, surface tension, and electronegativity of ePTFE.

62. ePTFE undergoes irreversible structural changes in the presence of microorganisms. The structural changes that ePTFE undergoes provides protection to the

microorganisms, allowing them to flourish and necessitating the total removal of ePTFE Bard Mesh.

63. The appropriate treatment for complications associated with the ePTFE Bard Mesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the product was intended to provide to the patient.

64. Defendants' product was designed and intended for intraperitoneal implantation, which required it to be placed in contact with internal organs, thus unnecessarily increasing the risks of adhesion, erosion, fistula formation, and other injuries.

65. When the ePTFE Bard Mesh was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products, including, but not limited to, a flat, non-coated, light-weight, large-pore, single-layer mesh placed away from the bowel.

66. The ePTFE Bard Mesh product costs significantly more than competitive products due to its unique design, even though the ePTFE Bard Mesh provided no benefit to consumers over other mesh types, and increased the risks to patients implanted with these devices.

67. Defendants' ePTFE Bard Mesh has a solid, flat, relatively smooth and continuous surface. Medical devices utilizing this design greatly increase the risk of tumor and cancer formation via the "Oppenheimer Effect":

A. In 1958, a study supported by a research grant from the National Cancer Institute titled The Latent Period in Carcinogenesis by Plastics in Rats and its Relation to the Presarcomatous Stage was published in the Journal of Cancer. **The presence of polymer in a sheet form appears to be of primary importance, as shown by the manifold increase in the percentage of tumors induced by this form, as opposed to textiles, sponges, powders, etc. This may act in some way as a block to the free interchange of tissue constituents, subjecting some cells to an altered environment and changing their pattern of growth. Whether the primary cause is lack of nutrients or oxygen, or the accumulation of products of metabolism, or even a freeing of the cell from some hormonal control, is not at present clear, but undoubtedly the cell is**

> **placed under conditions that are favorable to autonomous, unregulated growth. Plastics embedded subcutaneously in rodents in film or sheet form induce malignant tumors in significant numbers (up to 50%), but embedded in other forms, such as textiles, sponges, or powders, they induce tumors only rarely.**

Oppenheimer, B.S. et al, *The Latent Period in Carcinogenesis by Plastics in Rats and its Relations to the Presearcomatous Stage*. Journal of Cancer 1(11). 204 – 213 (1958).

B. In 1999, the World Health Organization's International Agency for Research on Cancer published *Surgical implants and Other Foreign Bodies*, which evaluated the carcinogenic risks of various surgical implants in humans. **Polymeric implants prepared as thin smooth films are possibly carcinogenic to humans.**

Surgical Implants and Other Foreign Bodies. IARC Monogr Eval Carcinog Risks Hum 74:1-409 (1999).

68. The numerous layers utilized to create the ePTFE Bard Mesh increases the intensity and duration of inflammation and foreign body response.

69. The ePTFE Bard Mesh implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to him.

70. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Decedent suffered injuries and damages as summarized in this Complaint.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

71. Plaintiff incorporates by reference the allegations in all prior paragraphs as if fully set forth herein.

72. When the ePTFE Bard Mesh was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the product were inadequate and defective. As described above, there was an unreasonable risk the product would not perform safely and effectively for the

purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

73. Defendants expected and intended the ePTFE Bard Mesh to reach users such as Plaintiff in the condition in which the product was sold.

74. Plaintiff CLARENCE DAVID WRIGHT and Plaintiff's physicians were unaware of the defects and dangers of ePTFE Bard Mesh, and were unaware of the frequency, severity and duration of the risks associated with the product.

75. The Defendants' Instructions for Use provided with the ePTFE Bard Mesh expressly understates and misstates the risks known to be associated specifically with the product, representing the associated complications such as inflammation merely as "possible complications." But the ePTFE Bard Mesh will always incite severe inflammation once implanted. The inflammation caused by the ePTFE Bard Mesh is chronic in nature and systemic, not acute localized inflammation. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the ePTFE Bard Mesh.

76. The Defendants' Instructions for Use for the product also failed to adequately warn Plaintiff's physician of numerous risks that Defendants knew or should have known were associated with the ePTFE Bard Mesh, including the risks of immunologic response, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

77. The Defendants' Instructions for Use for the ePTFE Bard Mesh failed to instruct physicians how much larger than the hernia defect the ePTFE Bard Mesh needed to be for an effective repair.

78. The Defendants' Instructions for Use for the ePTFE Bard Mesh failed to disclose the extent the ePTFE Bard Mesh would shrink, or that it would even shrink at all.

79. Defendants failed to adequately warn Plaintiff or his physicians about the necessity for invasive surgical intervention in the event of complications and failed to train the physician how to properly treat such complications when they occurred.

80. Defendants failed to adequately warn Plaintiff or his physicians that the surgical removal of the ePTFE Bard Mesh in the event of complications would leave the hernia unrepaired and much larger than the original; and would necessitate further, more complicated medical treatment to attempt to repair the same hernia that the failed product was intended to treat.

81. Defendants failed to adequately warn Plaintiff or his physicians that in the event of complications, the ePTFE Bard Mesh is more difficult to fully remove than other feasible hernia meshes that at all relevant times have been available.

82. Defendants failed to warn Plaintiff or his physicians that as a result of being implanted with the ePTFE Bard Mesh, Plaintiff would be at a higher risk of infection for the remainder of Plaintiff's life.

83. With respect to the complications listed in the Defendants' warnings, they provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with the ePTFE Bard Mesh were more frequent, more severe and longer lasting than those with safer feasible alternative hernia repair treatments.

84. If Plaintiff and/or his physician had been properly warned of the defects and dangers of the ePTFE Bard Mesh, and of the frequency, severity and duration of the risks associated with the product, Plaintiff would not have consented to allow it to be implanted, and Plaintiff's physician would not have implanted the product in Plaintiff.

85. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT IV: NEGLIGENCE

86. Plaintiff incorporates by reference the allegations in all prior paragraphs as of fully set forth herein.

87. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the ePTFE Bard Mesh, they failed to do so.

88. Defendants knew, or in the exercise of reasonable care should have known, that their product was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom it was implanted. Defendants knew or should have known that Plaintiff and his physician were unaware of the dangers and defects inherent in the ePTFE Bard Mesh.

89. Defendants knew or should have known that the Material Safety Data Sheet (MSDS) regarding the polypropylene used to manufacture their product prohibited permanently implanting polypropylene into the human body.

90. Defendants utilized non-medical grade polypropylene.

91. Defendants knew or should have known that polypropylene is not inert and will degrade, flake, chip, and disperse throughout the body once implanted.

92. Defendants knew or should have known that polypropylene induces a severe inflammatory response once implanted, and continues to induce a severe inflammatory response indefinitely or until removed.

93. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

94. Defendants knew or should have known that ePTFE is associated with high rates of severe, chronic infections.

95. Defendants knew or should have known that ePTFE degrades in the presence of bacteria.

96. Defendants knew or should have known that once ePTFE is infected, it is nearly impossible to permanently rid the infection and salvage the mesh.

97. Defendants knew or should have known that ePTFE is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

98. Defendants knew or should have known that implanting a solid, flat, relatively smooth and continuous disc shaped object would increase the rate of tumor formation and other adverse events.

99. Defendants knew or should have known that all subsequent operations carry a greater risk of infection after the patient has been implanted with ePTFE.

100. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the ePTFE Bard Mesh, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT V: BREACH OF IMPLIED WARRANTY

101. Plaintiff incorporates by reference the allegations in all prior paragraphs as if set forth fully herein.

102. At all material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the ePTFE Bard Mesh.

103. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner that Plaintiff and his implanting physician in fact used it; and Defendants impliedly warranted that the product and its component parts was of merchantable quality, safe and fit for such use, and adequately tested.

104. Defendants were aware that consumers, including Plaintiff and his physician, would implant their product as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' ePTFE Bard Mesh.

105. Defendants' ePTFE Bard Mesh was expected to reach, and did in fact reach consumers, including Plaintiff and his physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

106. Defendants breached various implied warranties with respect to ePTFE Bard Mesh, including the following:

A. Defendants represented to Plaintiff and his physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their product was safe. But at the same time they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;

B. Defendants represented to Plaintiff and his physician and healthcare providers that their product was safe and/or safer than other alternative procedures and devices. But at the same time they fraudulently concealed information demonstrating that the product was not safer than alternatives available on the market; and

C. Defendants represented to Plaintiff and his physician and healthcare providers that their product was more efficacious than alternative procedures and/or devices. But at the same time they fraudulently concealed information regarding the true efficacy of the ePTFE Bard Mesh.

107. In reliance upon Defendants' implied warranties, Plaintiff, individually, and/or by and through his physician, used the ePTFE Bard Mesh as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

108. Defendants breached their implied warranties to Plaintiff in that their product was not of merchantable quality, nor was it safe and fit for its intended use or adequately tested.

109. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT VI: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

110. Plaintiff incorporates by reference the allegations in all prior paragraphs as if fully set forth herein.

111. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the ePTFE Bard Mesh to Plaintiff.

112. On multiple occasions Defendants negligently concealed the harmful effects of the product from Plaintiff individually, and/or his physician. They continue to do so to this day.

113. On multiple occasions Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the ePTFE Bard Mesh to Plaintiff individually, and/or his physician. They continue to do so to this day.

114. Plaintiff was directly impacted by Defendants' negligence, in that he has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the product manufactured, sold and distributed by Defendants.

115. After Plaintiff sustained emotional distress, severe physical injuries, and economic loss, Defendants continued to negligently misrepresent the quality, safety, efficacy, dangers and contraindications of their product to Plaintiff and/or his physician.

116. Defendants continued to negligently misrepresent the quality, safety, efficacy, dangers and contraindications of their product to Plaintiff individually, and/or his physician, knowing that doing so would cause Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

117. As a proximate result of Defendants' conduct, Plaintiff has been injured. He has sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT VII: FRAUDULENT CONCEALMENT

118. Plaintiff incorporates by reference the allegations in all prior paragraphs as if fully set forth herein.

119. At all material times, it was known or knowable to Defendants that their product caused large numbers of complications. It also was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with the ePTFE Bard Mesh. It was known or knowable to Defendants that the safety and efficacy of their product had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion. And it was known or knowable to

Defendants that the product was not safe and effective. Defendants continued nonetheless to represent that their product was safe and effective.

120. Despite what was known or knowable to Defendants about the lack of safety and efficacy of their product, Defendants failed to disclose this information to Plaintiff, his physician, and/or public at large.

121. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and his physician the true facts concerning their product, *i.e.*, that the ePTFE Bard Mesh was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and was likely to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff CLARENCE DAVID WRIGHT was implanted with Defendants' product.

122. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the product because:

A. Defendants were in a superior position to know the true quality, safety, and efficacy of the ePTFE Bard Mesh;

B. Defendants knowingly made false claims about the safety and quality of the product in documents and marketing materials; and

C. Defendants fraudulently and affirmatively concealed the defective nature of their product from Plaintiff.

123. The facts Defendants concealed and/or did not disclose to Plaintiff were material facts that a reasonable person would have considered important in deciding whether to purchase and/or use Defendants' product.

124. At all material times, Defendants willfully, intentionally, and maliciously concealed facts from Plaintiff and his physician, with the intent to defraud them.

125. Defendants intentionally concealed or failed to disclose the true defective nature of the ePTFE Bard Mesh, so that Plaintiff would request and purchase it, and healthcare providers would dispense, prescribe, and recommend it. And Plaintiff justifiably acted or relied upon the concealed or non-disclosed facts to his detriment.

126. At all material times, neither Plaintiff nor his physician was aware of the facts above. Had they been aware of those facts, they would not have acted as they did, *i.e.*, by reasonably relying upon Defendants' representations of safety and efficacy, and by utilizing Defendants' product. Defendants' failure to disclose this information was a substantial factor in the selection by Plaintiff's physician of Defendants' product. Defendants' failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff as a patient.

127. As a direct and proximate result of Defendants' conduct, Plaintiff was injured.

COUNT VIII: NEGLIGENT MISREPRESENTATION

128. Plaintiff incorporates by reference the allegations in all prior paragraphs as if fully set forth herein.

129. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the ePTFE Bard Mesh had not been adequately tested and found to be a safe and effective treatment. Defendants breached that duty as their representations were false.

130. Defendants failed to exercise ordinary care in the representations concerning their product while they were involved in its manufacture, sale, testing, quality assurance, quality

control, and distribution in interstate commerce, because they negligently misrepresented the ePTFE Bard Mesh's high risk of unreasonable and dangerous adverse side effects.

131. Defendants also breached their duty in representing to Plaintiff, his physician, and the medical community that their product had no serious side effects different from older generations of similar products and/or procedures.

132. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew or had reason to know, that the ePTFE Bard Mesh had been insufficiently tested, or had not been tested at all; and that it lacked adequate and accurate warnings, and created a high risk, or a higher than acceptable reported and represented risk of adverse side effects. Those side effects include pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

133. As a direct and proximate result of Defendants' conduct, Plaintiff has been injured and sustained past and future severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

PUNITIVE DAMAGES

134. Plaintiff incorporates by reference the allegations in all prior paragraphs as if fully set forth herein.

135. Defendants failed to adequately test and study the ePTFE Bard Mesh to determine and ensure that the product was safe and effective prior to releasing it for sale for permanent human implantation. Further, Defendants continued to manufacture and sell the product after obtaining knowledge and information that it was defective and unreasonably unsafe.

136. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the ePTFE Bard Mesh, they developed, designed and sold the ePTFE Bard Mesh, and continue to do so, because the product has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective product, including the risk of failure and serious injury, such as suffered by Plaintiff.

137. At all material times, Defendants knew or should have known that ePTFE Bard Mesh was inherently more dangerous with respect to the following: the risk of foreign body response, allergic reaction, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments to cure the conditions proximately related to the use of the product, as well as the other permanent and lasting severe personal injuries.

138. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the ePTFE Bard Mesh, which deprived Plaintiff and his implanting physician of vitally necessary information with which to make a fully informed decision about whether to use the product.

139. At all material times, Defendants also knew and recklessly and/or intentionally disregarded the fact that their product can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatments. But Defendants recklessly failed to advise the medical community and the general public, including Plaintiffs, of that fact.

140. At all material times, Defendants intentionally misstated and misrepresented data; and they continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by or associated with the ePTFE Bard Mesh.

141. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the ePTFE Bard Mesh, with its increased risk of side effects and serious complications, Defendants continue to aggressively market the product to the medical community and to consumers without disclosing the true risk of the complications and side effects.

142. When Plaintiff CLARENCE DAVID WRIGHT was implanted with the ePTFE Bard Mesh and since then, Defendants have known the product was defective and unreasonably dangerous. But they continued to manufacture, produce, assemble, market, distribute, and sell ePTFE Bard Mesh so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the product to members of the public, including Plaintiff.

143. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the product, so as to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiff.

144. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff CLARENCE DAVID WRIGHT demands judgment against Defendants individually, jointly, and severally. Plaintiff also requests compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiff CLARENCE DAVID WRIGHT demands judgment against Defendants, individually and jointly and severally, and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff; permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, mental anguish and other damages incurred by Plaintiffs, together with interest and costs as provided by law;

ii. Restitution and disgorgement of Defendants' profits;

iii. Punitive or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. Past and future costs of all proceedings;

vi. All ascertainable economic damages;

vii. Prejudgment interest on all damages as allowed by law; and

viii. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff CLARENCE DAVID WRIGHT hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

Dated: August 10, 2018

By: /s/ C. Brett Vaughn
C. Brett Vaughn (MO Bar No. 66974)
Adam M. Evans (MO Bar No. 60895)
Hollis Law Firm, P.A.
5100 W. 95th St.
Prairie Village, KS 66207
(913) 385-5400
(913) 385-5402 (fax)
E-mail: brett@hollislawfirm.com
adam@hollislawfirm.com

Andrea J. Giovannone (CA Bar No. 287358)
Pro hac vice forthcoming
Gregory Rueb (CA Bar No. 154589, District of Columbia Bar No. 1033707)
Pro hac vice forthcoming
Stephen "Buck" Daniel (GA Bar No 777514)
Pro hac vice forthcoming
Dalimonte Rueb, L.L.P.
1250 Connecticut Ave. NW, Ste. 200
Washington, District of Columbia 20036
Telephone: 202.538.2790
E-mail: andrea@drlawllp.com
greg@drlawllp.com
buck@drlawllp.com

Attorneys for Plaintiffs CLARENCE DAVID WRIGHT and SHARON K. WRIGHT